



Miracle-Ear®

October 16, 2000

Honorable Donna E. Shalala
Secretary of Health and Human Services
200 Independence Avenue, S.W. Room 615F
Washington, D.C. 20201

Dear Secretary Shalala,

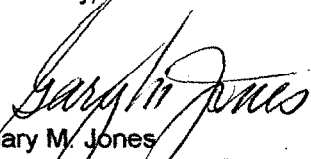
I am a small business owner in the cities of Ontario, Claremont and West Covina, providing hearing healthcare services to over **1600 hearing impaired people** in California. I have just been made aware that after more than eight, yes 8, years of rewriting, the Food and Drug Administration is now rushing to propose new rules governing the way hearing aids are sold in the United States. These rules would dramatically increase the cost of hearing health care and reduce access to hearing healthcare providers such as me.

The regulations, as proposed, will put me out of business! A business that was established back in 1958. Presently, all three members of the *hearing healthcare delivery team* (hearing aid specialists, audiologists and physicians) are recognized as qualified entry points into the hearing healthcare system. The rule FDA is rushing to put forth could eliminate hearing aid specialists like me from the marketplace. The FDA reportedly favors allowing each state to determine the conditions for dispensing hearing aids. This will create inconsistency and confusion and will launch a 50-state effort by audiologists to install themselves as the sole gatekeepers to hearing healthcare without any medical or health policy justification.

The State of California requires ALL in the business of dispensing hearing aids to pass the same written and practical examinations, both laymen and audiologists. As you may have seen in the AARP "Consumer Guide to Hearing Aids" which found that "almost everyone with a hearing loss hears better with a hearing aid, yet only 20% of those who need a hearing aid have one." Please don't let your department erect unwarranted access barriers to this safe and effective medical device.

Please don't let the FDA publish its proposed hearing aid rule.

Sincerely,


Gary M. Jones
Hearing Instrument Specialist
State of California License #HA3682
Malcolm Glen Corporation

GMJ/js 93N 0372
cc: File

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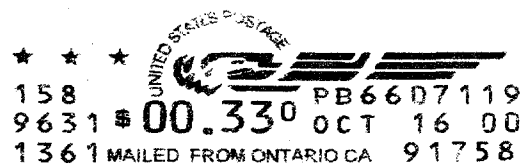
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